

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Patent Application of:** Hana Golding

**Application No.:** 10/536,860

**Confirmation No.:** 4611

**Filed:** January 6, 2006

**Art Unit:** 1648

**For:** METHODS FOR DETECTING INVASION OF  
A CELL

**Examiner:** Stacy Brown Chen

Mail Stop: AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATION OF ELECTRONIC FILING UNDER 37 C.F.R. §1.8**

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with 37 C.F.R. §1.6(a)(4): on June 20, 2011; Mail Stop: Amendment. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Gabriel J. McCool  
Name of Person signing certificate

/Gabriel J. McCool/  
Signature

**AMENDMENT AND RESPONSE TO THE FINAL OFFICE ACTION**

Dear Commissioner:

Applicants submit this paper in response to the final Office Action, mailed April 19, 2011. The Action set a THREE MONTH shortened statutory period for reply. However, this paper is being submitted within TWO MONTHS of the mailing date of the Action, i.e., by June 20, 2011 (as June 19 fell on a Sunday). Thus, the shortened statutory period will expire on the date an Advisory Action is mailed where the mailing date of the Advisory Action is not until after the end of the THREE MONTH shortened statutory period for reply. No fees are believed to be due with this filing. However, Applicants authorize the Director to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No.: 65831(47992).

**Amendments to the claims** are reflected in the listing of claims beginning on page 2.

**Remarks/arguments** begin on page 5 of this paper.

## AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the application.

What is claimed is:

1. (Currently amended) A rapid vaccinia neutralization assay comprising:

incubating a mixture comprising at least one cell, a vaccinia virus comprising a reporter gene encoding  $\beta$ -galactosidase ~~an enzyme~~, and a candidate antibody under conditions wherein the vaccinia virus can invade the cell; and

detecting the activity of the  $\beta$ -galactosidase ~~enzyme~~ within the cell,

wherein a decrease in the  $\beta$ -galactosidase ~~enzyme~~ activity in the cell due to the candidate antibody, relative to a control cell having not been contacted with the candidate antibody, indicates that the candidate antibody decreases invasion of the cell by the vaccinia virus, and

wherein the assay is completed within 24 hours, and wherein the vaccinia virus is vSC56 or vSC8.

- 2-4. (Cancelled)

5. (Currently amended) The assay of claim 1, wherein ~~the vaccinia virus is vSC56~~, said reporter gene of the virus encoding  $\beta$ -galactosidase is under control of a late vaccinia promoter P11.

6. (Cancelled)

7. (Currently amended) The assay of claim ~~5~~1, wherein ~~the vaccinia virus is vSC8~~, said reporter gene of the virus encoding  $\beta$ -galactosidase ~~is~~ under control of a synthetic E/L promoter.

8. – 13. (Cancelled)

14. (Previously presented) The assay of claim 1, wherein the candidate antibody is a vaccinia IgG (VIG), a monoclonal antibody, a polyclonal antibody, or an altered antibody.

15. (Previously presented) The assay of claim 1, wherein the candidate antibody inhibits invasion of the cell by associating with the cell, or associating with the vaccinia virus, or by associating both with the cell and vaccinia virus.

16. (Cancelled)

17. (Previously presented) The assay of claim 1, wherein the cell is a mammalian cell.

18. (Previously presented) The assay of claim 17, wherein the cell is a human cell.

19-20. (Cancelled)

21. (Previously presented) The assay of claim 18, wherein the cell is selected from the group consisting of a lymphoid cell, a pulmonary cell, and an intestinal cell.

22 – 130. (Cancelled)

131. (Currently amended) The assay of claim ~~13~~1, wherein the method is predictive of protection against viral lethality in a mouse model *in vivo*.

132. (Currently amended) The assay of claim ~~13~~1, wherein the assay is a high throughput assay.

133. (Previously presented) The assay of claim 1, wherein the method further comprises quantitation of invasion of a cell by an invasin using of a standard curve.

134. (Previously presented) The assay of claim 133, wherein the  $r^2$  of the standard curve is  $>0.9$ .

135. (Previously presented) The assay of claim 1, wherein the method is performed in a plate comprising 96-wells.

136. (Previously presented) The assay of claim 1, wherein the method provides results that are comparable to results obtained with a PRNT neutralization assay.

137-138. (Cancelled)

139. (Previously presented) The assay of claim 131, wherein the mouse model is a SCID mouse model.

**REMARKS****A.    *Introductory remarks***

Claims 1, 5, 7, 12-15, 17, 18, 21 and 131-139 were pending before the Office. Applicants have amended claims 1, 5, 7, 131 and 132 and canceled claims 12, 13, 137 and 138, without prejudice. Accordingly, claims 1, 5, 7, 14-15, 17, 18, 21, 131-136 and 139 will be pending upon entry of these amendments.

The amendments have been made solely to claim more fully the invention and/or to expedite prosecution of the present application and should in no way be construed as an acquiescence to any of the Examiner's rejections in the Office action issued in the present application. Applicants reserve the right to pursue the subject matter of the claims as originally filed or similar claims in one or more subsequent applications.

Support for the amendments and new claims can be found throughout the application, including the specification, drawings, examples and claims, as originally filed. No new matter has been added by these amendments.

**B.    *The claim rejection under 35 U.S.C. §112, first paragraph, is overcome***

Claims 5 and 7 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. According to the Action, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention in view of the fact that the recited vSC56 and vSC8 vaccinia viruses are not apparently available via a public strain depository pursuant to the terms of the Budapest Treaty. Applicants respectfully request an abeyance of the 35 U.S.C. §112, first paragraph, rejection until such time as allowable subject matter has been found and to allow Applicants an opportunity to submit the recited viruses to a public depository.

**C.    *The claim rejections under 35 U.S.C. §103(a) are overcome***

The Examiner has maintained the rejection of claims 1, 12-15, 17, 18, 21, 131, 136 and 139 under 35 U.S.C. 103(a) as allegedly being unpatentable over Hooper et al. (U.S. Patent No. 6,451,309, "Hooper") in view of Auewarakul et al. (Asian Pacific Journal of Allergy and

Immunology, 2001, 19:139-144, cited in IDS filed 3/29/07, “Auewarakul”) and Dominguez et al. (Journal of Immunological Methods, 1998, 220:115-221, “Dominguez”). **The Office Action expressly states that claims 5 and 7 are not included in the Section 103 rejection.** See Office Action, page 5. The Office Action also indicates that claims 132 and 135 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hooper, Auewarakul, and Dominguez as applied to claim 1, in further view of Briskin et al. (U.S. Patent No. 6,319,675, “Briskin”). Further, claims 133 and 134 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hooper, Auewarakul, and Dominguez as applied to claim 1, in further view of BD Biosciences (Introduction to Flow Cytometry: A Learning Guide, Manual Part Number: 11-11032-01, April, 2000) (“BD Biosciences”). Lastly, claims 137 and 138 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hooper, Auewarakul, and Dominguez as applied to claim 1, in further view of Chakrabarti et al., Molecular and Cellular Biology, 1985, 5(12):343-3409) (“Chakrabarti”).

Applicants respectfully disagree with the Examiner and traverse the rejections. Nevertheless, without wishing or intending to acquiesce to any of the Examiner’s bases for the rejections, Applicants have agreed to incorporate into claim 1 the limitations of claims 5 and 7, thereby obviating each of the rejections. The remaining claims depend—either directly or indirectly—from claim 1; thus, each of the pending claims incorporate the features of claims 5 and 7. Accordingly, each of the Section 103 rejections are overcome with respect to all of the pending claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the Section 103 rejections.

### **CONCLUSION**

In view of the amendments and remarks herewith, the application is believed to be in condition for allowance. Applicants respectfully request entry of this paper, favorable reconsideration and withdrawal of the rejections, and prompt issuance of a Notice of Allowance. If a telephone conversation with Applicants' attorney(s) would help to expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned.

Respectfully submitted,

Date: June 20, 2011

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